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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/521,401	09/12/2005	Clifford Charles Shone	MSQ01-003-US	2849

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EVAN LAW GROUP LLC
600 WEST JACKSON BLVD., SUITE 625
CHICAGO, IL 60661

EXAMINER	
GANGLE, BRIAN J	
ART UNIT	**PAPER NUMBER**
1645	
MAIL DATE	**DELIVERY MODE**
11/19/2007	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/521,401	SHONE ET AL.	
	Examiner	Art Unit	
	Brian J. Gangle	1645	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *19 January 2007*.

2a)☐ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *51-72* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☐ Claim(s) _____ is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☒ Claim(s) *51-72* are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Election/Restrictions

Restriction is required under 35 U.S.C. 121 and 372.

This application contains the following inventions or groups of inventions which are not so linked as to form a single general inventive concept under PCT Rule 13.1.

In accordance with 37 CFR 1.499, applicant is required, in reply to this action, to elect a single invention to which the claims must be restricted.

Group I, claim(s) 51, 59-63 and 70-71, drawn to compositions comprising a therapeutic agent which inhibits a Rho GTPase, and a neuronal cell targeting component comprising an Hc domain of botulinum C1 toxin.

Group II, claim(s) 52-58, drawn to compositions comprising a therapeutic agent which inhibits a Rho GTPase, a neuronal cell targeting component comprising an Hc domain of botulinum C1 toxin, and a translocation domain.

Group III, claim(s) 64, 66, 68, and 69, drawn to compositions comprising a therapeutic agent which inhibits a Rho GTPase and a neuronal cell targeting component comprising an Hc domain of botulinum C1 toxin, wherein the therapeutic agent and Hc domain are joined together directly or via a linker molecule.

Group IV, claim(s) 65 and 67, drawn to compositions comprising a therapeutic agent which inhibits a Rho GTPase, a neuronal cell targeting component comprising an Hc domain of botulinum C1 toxin, and a translocation domain, wherein the therapeutic agent, Hc domain, and translocation domain are joined together directly or via a linker molecule.

Group V, claim(s) 72, drawn to a method of making compositions comprising a therapeutic agent which inhibits a Rho GTPase and a neuronal cell targeting component comprising an Hc domain of botulinum C1 toxin by expressing a DNA encoding the therapeutic agent and the neuronal cell targeting domain.

Domain Election Requirement Applicable to Groups I-II

In addition, Groups I-II, detailed above, read on patentably distinct translocation domains and/or therapeutic agents. Each combination of translocation domains and/or therapeutic agents is patentably distinct because they are molecules with differing biochemical and immunological properties and a further restriction is applied to Groups I-II.

For Group I, applicant must further elect:

1. a type of therapeutic agent or combination thereof(from claim 59), and if enzyme is chosen, the specific source and enzyme from claims 61-63.

For Group II, applicant must further elect:

2. a specific translocation domain (a translocation domain from *C. botulinum,* a translocation domain from *C. butyricum,* a translocation domain from *C. argentinense,* a translocation domain from *C. tetani*, diptheria toxin, *Pseudomonas* exotoxin A, influenza virus haemagglutinin fusogenic peptides or amphiphilic peptides, or botulinum C1 toxin); and

Applicant is advised that examination will be restricted to only the elected combination of translocation domains and /or therapeutic agent and this should not be construed as a species election.

The inventions listed as Groups I-IV do not relate to a single general inventive concept under PCT Rule 13.1 because, under PCT Rule 13.2, they lack the same or corresponding special technical features for the following reasons:

The technical feature linking Groups I-IV appears to be a composition comprising a therapeutic agent which inhibits a Rho GTPase, a neuronal cell targeting component comprising an Hc domain of botulinum C1 toxin.

However, Shone *et al.* (PCT Publication WO 00/28041, 2000, IDS filed 1/18/2005) disclose a composition comprising superoxide dismutase linked to a neuronal cell targeting domain (see abstract). Shone *et al.* discuss botulinum C1 toxin as a targeting neurotoxin (page 4, lines 20-25). As evidenced by Heo *et al.* (J. Biol. Chem., 280:31003-31010, 2005), superoxide dismutase abolishes Rac1 guanine nucleotide dissociation, which indicates that it inhibits the activity of a Rho GTPase (Rac1) (page 31004, column 2, paragraph 1).

Therefore, the technical feature linking the inventions of Groups I-IV does not constitute a special technical feature as defined by PCT Rule 13.2, as it does not define a contribution over the art.

The examiner has required restriction between product and process claims. Where applicant elects claims directed to the product, and the product claims are subsequently found allowable, withdrawn process claims that depend from or otherwise require all the limitations of the allowable product claim will be considered for rejoinder. All claims directed to a nonelected process invention must require all the limitations of an allowable product claim for that process invention to be rejoined.

In the event of rejoinder, the requirement for restriction between the product claims and the rejoined process claims will be withdrawn, and the rejoined process claims will be fully

examined for patentability in accordance with 37 CFR 1.104. Thus, to be allowable, the rejoined claims must meet all criteria for patentability including the requirements of 35 U.S.C. 101, 102, 103 and 112. Until all claims to the elected product are found allowable, an otherwise proper restriction requirement between product claims and process claims may be maintained. Withdrawn process claims that are not commensurate in scope with an allowable product claim will not be rejoined. See MPEP § 821.04(b). Additionally, in order to retain the right to rejoinder in accordance with the above policy, applicant is advised that the process claims should be amended during prosecution to require the limitations of the product claims. **Failure to do so may result in a loss of the right to rejoinder**. Further, note that the prohibition against double patenting rejections of 35 U.S.C. 121 does not apply where the restriction requirement is withdrawn by the examiner before the patent issues. See MPEP § 804.01.

Applicant is advised that the reply to this requirement to be complete must include (i) an election of a species or invention to be examined even though the requirement be traversed (37 CFR 1.143) and (ii) identification of the claims encompassing the elected invention.

The election of an invention or species may be made with or without traverse. To reserve a right to petition, the election must be made with traverse. If the reply does not distinctly and specifically point out supposed errors in the restriction requirement, the election shall be treated as an election without traverse.

Should applicant traverse on the ground that the inventions or species are not patentably distinct, applicant should submit evidence or identify such evidence now of record showing the inventions or species to be obvious variants or clearly admit on the record that this is the case. In either instance, if the examiner finds one of the inventions unpatentable over the prior art, the evidence or admission may be used in a rejection under 35 U.S.C.103(a) of the other invention.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Brian J. Gangle whose telephone number is (571) 272-1181. The examiner can normally be reached on M-F 8-4:30.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's acting supervisor, Bruce Campell can be reached on (571) 272-0974. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Brian Gangle
AU 1645

ROBERT A. ZEMAN
PRIMARY EXAMINER